

Food and Drug Administration Rockville MD 20857

APR - 5 1999

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The Honorable Ralph M. Hall
House of RepresentativesWashington, D.C. 20515-4304

Dear Mr. Hall:

Thank you for your letter of March 22, 1999, on behalf of several of your constituents, regarding dietary supplements containing ephedrine alkaloids. Ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. The ephedrine alkaloids in dietary supplements are naturally occurring stimulants and usually are derived from one of several species of herbs of the genus Ephedra, sometimes called Ma huang or Chinese Ephedra.

On June 4, 1997, the Food and Drug Administration (FDA or the Agency) published a proposed rule in the <u>Federal</u> <u>Register</u> (FR) regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. In the proposed rule, the Agency is proposing:

- to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a 6hour period or a total daily intake of 24 mg or more of ephedrine alkaloids;
- to require that the label of dietary supplements that contain ephedrine alkaloids state, "Do not use this product for more than 7 days";
- to prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids;
- to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building);

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- to require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that, "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and
- to require specific warning statements to appear on product labels.

The proposal also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements.

FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products which contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors, and headaches, to seizures, strokes, and death. As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products which contained, or were suspected of containing, ephedrine alkaloids. adverse events reports showed consistent patterns of illness and injury among otherwise healthy individuals and those with underlying diseases or conditions. continues to receive additional reports of adverse events associated with the use of these products.

The proposed measures were developed based on FDA's review of its adverse event reports, the scientific literature, and public comments reviewed by the Agency, including comments generated by an October 1995 advisory working group public meeting and an August 1996 public meeting of FDA's Food Advisory Committee. These experts suggested a number of steps the Agency might take to reduce injuries associated with the use of dietary supplements containing ephedrine alkaloids. If implemented, the proposed rule will reduce the risk of adverse events for consumers who use these products.

FDA allowed a 75-day comment period on the proposed rule. On September 18, 1997 (62 FR 48968), that comment period was reopened for an additional 75 days until December 2, 1997. FDA invited written comments on the proposal from the public and industry. All comments received will be reviewed and considered by the Agency in developing the final rule.

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We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Melinda K. Plaisier Interim Associate Commissioner for Legislative Affairs

Dockets Management Branch cc:

(Docket #95N-0304)

RALPH M. HALL 4TH DISTRICT, TEXAS

Congress of the United States

House of Representatives

Washington, DC 20515-4304

March 22, 1999

COMMERCE ENERGY AND POWER RANKING MINORITY MEMBER

HEALTH AND ENVIRONMENT
FINANCE AND HAZARDOUS MATERIALS

SCIENCE SPACE AND AERONAUTICS ENERGY AND ENVIRONMENT

Ms. Diane E. Thompson Legislative Affairs Food and Drug Administration 5600 Fisher Lane Rockville, MD 20857-0001

Dear Ms. Thompson:

I have received ten postcards on a subject which is within the jurisdiction of your office. These constituents are writing to voice their opposition to a proposed rule (62FED.REG.30678.) Apparently, this rule would limit levels of ephedrine, found in a dietary supplement, known as Ma Huang.

These constituents would like to have their voices counted among those who oppose this proposed rule, and they have asked that I register their comments with your office. In case you need the actual names and addresses of these individuals I am enclosing the cards which have been sent to me. Besides registering the names of these individuals among those opposing this proposed regulation, I also ask that your office send me a brief response explaining the position of the Federal Food and Drug Administration, FDA on this dietary supplement.

You may direct any of your communications to my office, on this subject to Ms. Marsha Shasteen, who can be reached at my Washington office.

Sincerely,

Ralph M. Hall / Member of Congress

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Dear Representative Range Hall

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